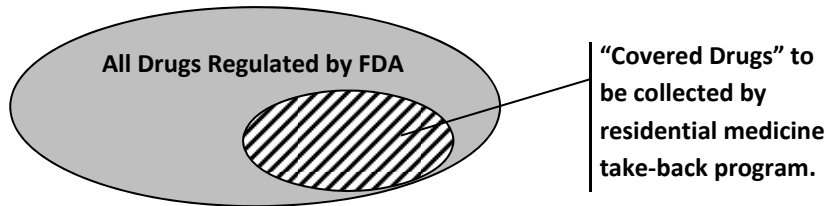


## Definitions of Drugs and Types of Drug



### Categories of Drugs: Prescription Medicines and Over-the-Counter Medicines

	Prescription Medicines	Over-the Counter Medicines
<b>Regulatory term(s)</b>	<p>FDA: <b>Prescription drug.</b></p> <p>WA state: <b>legend drug</b></p> <p>This term arises because prescription drugs must have a legend (or notice) on the label that it is dispensed with a legal prescription.</p>	<p>FDA: <b>Over-the-counter drug.</b></p> <p>also called:</p> <p><b>OTC</b></p> <p><b>Nonprescription</b></p> <p>WA state: <b>nonlegend drug</b></p>
<b>FDA Definition</b>	<p>Prescription Drug Product</p> <p>A drug product that requires a doctor's authorization to purchase.</p>	<p>Over-the-Counter Drugs (OTC)</p> <p>Drugs that are safe and effective for use by the general public without a doctor's prescription.</p>
<b>Layperson explanation</b>	<p>Prescription medicines are required by federal or state law to be dispensed to an individual only through a prescription from a licensed physician or other licensed health provider.</p> <p>Patients should only take prescription medicines as directed while under a doctor's care. Prescription medicines must be dispensed by a licensed pharmacy or by a doctor or health care facility. Only the specific individual listed on the label is legally allowed to use a prescription medicine.</p>	<p>Over-the-counter medicines can be purchased by consumers without a prescription. Consumers can "self-medicate" with OTC drugs and are advised to follow directions on the label for proper use.</p> <p>Over-the-counter medicines can be purchased off the shelf at pharmacies, grocery stores, mini-marts, big box stores, etc...</p>
<b>WA State Definition in SSB 5234, medicine take-back bill</b>	<p>"Legend drug" means any drugs, including controlled substances under chapter 69.50 RCW, that are required by any applicable federal or state law or regulation to be dispensed by prescription only or are restricted to use by practitioners only.</p>	<p>"Nonlegend drug" means any drugs that may be lawfully sold without a prescription.</p>

## Definitions of Drugs and Types of Drug

### Definition of “drug” from the federal Food Drug & Cosmetics Act.

(g)(1) The term “drug” means

(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and

(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and

(C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and

(D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim.

A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.

### Definition of “cosmetics” from the federal Food Drug & Cosmetics Act

The FD&C Act defines cosmetics by their intended use, as

"articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body...for cleansing, beautifying, promoting attractiveness, or altering the appearance" [FD&C Act, sec. 201(i)].

Some drugs are regulated by FDA as both a drug and a cosmetic. Examples of OTC drugs that are also cosmetics include: sunscreens, toothpaste, dandruff shampoos, acne treatments, and deodorants.

These items are considered personal care products or cosmetics by the public.

### Definition of Biologic Products from FDA

Biologic products are made from a living organism or its products, such as proteins, antibodies, or cells.

FDA regulations define a “biologic product” or biologic drug as any virus, therapeutic serum, toxin, antitoxin or analogous product applicable to the prevention, treatment or cure of diseases or injuries of man (21 CFR 600.3(h)). Many biologic drugs are used only in clinical settings, but increasingly, biologic drugs are being developed in forms suitable for home use, such as pills or self-injectables. Examples: insulin, human growth hormone, Enbrel (for arthritis).

### Combination Products

The FDA defines “Combination products” as therapeutic and diagnostic products that combine drugs, devices, and/or biological products.

Drug patches that dispense pharmaceuticals dermally are a drug/device combination. Prescription drug patches are available to treat pain, Parkinson’s, attention deficit disorder, depression, and other diseases and disorders. Also nicotine patches are sold over-the-counter as smoking cessation aids.

More info at: <http://www.fda.gov/CombinationProducts/AboutCombinationProducts/default.htm>

### FDA’s Definition and Regulation of Dietary Supplements – Not Drugs

The FDA does not regulate dietary supplements as drugs, rather they are under the umbrella of “foods”.

Manufacturers are not required to obtain pre-market FDA approval. A dietary supplement is a product intended for ingestion that contains a "dietary ingredient" intended to add further nutritional value to (supplement) the diet. A "dietary ingredient" may be one, or any combination, of the following substances:

- a vitamin
- a mineral
- an herb or other botanical
- an amino acid
- a dietary substance for use by people to supplement the diet by increasing the total dietary intake .















# What Can You Take Back?

Learn about how to use medicine take-back programs. (from <http://www.takebackyourmeds.org/what-you-can-do/what-to-takeback>)

**All medicines that your family and your pets use should be properly disposed of at a drug take-back program.** More detailed information about specific medicines and other types of medical waste is provided below.

Some prescription medicines like narcotics and stimulants are [controlled substances](#) and can only be returned to law enforcement locations. Many of the listed law enforcement sites accept all medicines. Pharmacy sites can accept most medicines, except controlled substances.

Some other medical waste - like sharps and thermometers -- should be properly disposed in other ways. Find out what to do with your [items that cannot be returned](#) to the Medicine Take-Back.

Yes: Items Accepted 	No: Items Not Accepted 
<p>Prescription medications: law enforcement locations can accept all prescription medicines. Pharmacies can accept most prescription medicines but not <a href="#">controlled substances</a>.</p> 	<p>NO: Pharmacies cannot accept prescription medicines that are <a href="#">controlled substances</a>. Take these to a law enforcement location.</p>
<p>Over-the-counter medications.</p> 	<p>NO: Needles/ Lancets/ Syringes</p> 
<p>Vitamins</p> 	<p>NO: Thermometers</p> 
<p>Medications for pets</p> 	<p>NO: Aerosol cans</p> 
<p>Medication samples</p>	<p>NO: Hydrogen Peroxide</p>
<p>Medicated ointments/lotions</p> 	<p>NO: Empty containers</p> 
<p>Inhalers</p> 	<p>NO: Bloody or infectious waste</p>
<p>Liquid medicine in glass or leak-proof containers (up to 12 oz.)</p> 	<p>NO: Personal care products (non-medicated shampoo, etc).</p>  <p>NO: Business waste</p>

# Drug Abuse and Preventable Poisoning from Over-the-Counter Medicines

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## Drug Abuse

One of the most abused over-the-counter medicines by teens is cough syrup containing Dextromethorphan (DXM). DXM, a cough suppressant found in 310 FDA registered over-the-counter cough and cold medicines can produce euphoric, psychedelic, and dissociative effects similar to psychotropic drugs when taken in high doses.

- 10% of teens say they have taken non-prescription cough medicine to get high<sup>1</sup>
- 5,962 emergency department visits for nonmedical use of cough medicines involved patients aged 12 to 20 in 2004<sup>2</sup>.
- In 2006, 3.1 million youth and young adults aged 12 to 25 said they had used an over-the-counter cough and cold medication to get high - with almost 1 million reporting they had done so in the past year<sup>3</sup>
- From 1999 to 2004, there was a seven-fold increase in cases related to the abuse of DXM reported to poison control centers nationwide. Most of these cases were among 15- and 16-year-olds.<sup>4</sup>
- Fewer than half of teens believe abusing cough medicine to get high is risky<sup>4</sup>.

Although not as commonly reported as DXM, other over-the-counter medicines that are abused by teens include<sup>5</sup>:

- Caffeine stimulants like No-Doz, etc.
- Antihistamines like Benadryl containing diphenhydramine
- Decongestants like Sudafed containing pseudoephedrine
- Weight loss supplements containing ma haung or ephedra
- Sleep aids containing doxylamine, like Unisom, etc.
- Motion sickness treatments with dimenhydrinates, like Dramamine

## Preventable Poisonings

- In 2011, ibuprofen, acetaminophen, antihistamines and topical ointments such as hydrocortisone and triple antibiotics were the over-the-counter medicines reported most frequently to Washington Poison Control for poisonings of children under age 5<sup>6</sup>.
- Of the estimated 71,224 emergency department visits made annually for medication overdoses by children under age 18, 82% involved children under age 5 and commonly available over-the-counter medications were implicated in 34% of visits. Acetaminophen, cold and cough products, NSAIDs and antihistamines were the most frequently reported<sup>7</sup>.
- 26% of child poisoning deaths in Washington were caused by someone else's over-the-counter medications and 32% were caused by someone else's prescription medications<sup>8</sup>.
- About 165 young kids — or roughly four school busloads of children — are seen in emergency rooms every day in the US after getting into medications (both over-the-counter and prescription)<sup>9</sup>.
- Medication deaths (both over-the-counter and prescription) as a percentage of all child poisoning deaths have nearly doubled since 1970<sup>10</sup>.

## Potential for Over-the-Counter Medication Adverse Events

FDA warning labels show many over-the-counter medicines are not safe to give young children *at any dose* – making them especially hazardous when accidentally ingested by a small child. Aspirin, cough and cold, antihistamines and bismuth subsalicylate (i.e. Pepto-Bismol) are just a few examples of common over-the-counter medicines that are particularly hazardous to young children.

For all consumers, many over-the-counter medicines carry warning labels about importance of not exceeding recommended dosages, cautions about drug interactions, and cautions about use by specific individuals that demonstrate the risks of improper use or unintentional overdoses from over-the-counter medications<sup>11</sup>.

More, very potent, drugs are expected to switch from prescription to over-the-counter by 2016 according to the pharmaceutical industry. Prescription drugs used primarily for chronic therapy treatment such as hypertension, dermatology, lipid-lower, osteoporosis, arthritis and incontinence is expected to switch from prescription to nonprescription status.<sup>12</sup>

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<sup>1</sup> Partnership for a drug-free America. 2009. The Partnership Attitude Tracking Study (PATS) Teens 2008 Report. Released February 26, 2009. Available online at: [http://www.drugfree.org/wp-content/uploads/2011/04/Full-Report-FINAL-PATS-Teens-2008\\_updated.pdf](http://www.drugfree.org/wp-content/uploads/2011/04/Full-Report-FINAL-PATS-Teens-2008_updated.pdf)

<sup>2</sup> Drug Abuse Warning Network. 2006. Emergency Department Visits Involving Dextromethorphan. The DAWN Report. Available online at: <http://www.samhsa.gov/data/2k6/TNDR32DXM/TNDR32DXM.htm>

<sup>3</sup> Office of Applied Studies, Substance Abuse and Mental Health Services Administration (SAMHSA). 2008. National Survey on Drug Use and Health. Misuse of Over-the-Counter Cough and Cold Medications among Persons Aged 12 to 25. January 10, 2008. Available online at: <http://www.samhsa.gov/data/2k8/cough/cough.htm>.

<sup>4</sup> Office of National Drug Control Policy. 2008. Prescription for Danger, A Report on the Troubling Trend of Prescription and Over-the-Counter Drug Abuse Among the Nation's Teens. Available online at: [http://www.theantidrug.com/pdfs/prescription\\_report.PDF](http://www.theantidrug.com/pdfs/prescription_report.PDF)

<sup>5</sup> Trobledteen101.com is a private company that provides a clearinghouse of information on parenting and treatment programs for troubled youth. Available online at: <http://www.troubledteen101.com/articles50.html>

<sup>6</sup> Washington Poison Control. 2011. Top 10 in 2011.

<sup>7</sup> Schillie, S.F., et al. 2009. Medication overdoses leading to emergency department visits among children. Am J Prev Med 2009. Available online at: [http://www.ajpm-online.net/webfiles/images/journals/amepre/AMEPRE\\_2545.pdf](http://www.ajpm-online.net/webfiles/images/journals/amepre/AMEPRE_2545.pdf)

<sup>8</sup> Sabel, J. (2004). Washington State Childhood Injury Report – Poisoning Chapter. WA DOH. Available online at: [http://www.doh.wa.gov/hsqa/emstrauma/injury/pubs/wscir/WSCIR\\_Poisoning.pdf](http://www.doh.wa.gov/hsqa/emstrauma/injury/pubs/wscir/WSCIR_Poisoning.pdf)

<sup>9</sup> Centers for Disease Control and Prevention. Put Your Medicines Up and Away and Out of Sight. Centers for Disease Control and Prevention Website. Available from: <http://www.cdc.gov/features/medicationstorage/>. Accessed February 9, 2012.

<sup>10</sup> Centers for Disease Control and Prevention. CDC WONDER Compressed Mortality File, Underlying Cause-of-Death. Centers for Disease Control and Prevention Website. Available from: <http://wonder.cdc.gov/mortSQL.html>. Accessed February 15, 2012.

<sup>11</sup> OTCsafety.org. <http://otcsafety.org/en/ingredients/> A website on over-the-counter medicine safety from the Consumer Healthcare Products Association.

<sup>12</sup> The Pharma Letter. Accessed online August 13, 2012 at: <http://www.thepharmaletter.com/file/107173/major-global-expansion-of-rx-to-otc-switch-forecast-by-2016.htm>.

# Drug Companies Whose Products Are Distributed in Washington State by Cardinal Health (initial staff review)

Cardinal Health, a large local distributor of prescription and over-the-counter medicines, provided a list of manufacturers whose products they distribute in Washington State. Manufacturer is a very broad term that includes companies that use chemical or biological processes to create the drug product, as well as companies that package, label, process, and format drugs into tablets, liquids, gels, etc.

Cardinal Health's list of manufacturers was sorted by LHWMP staff as follows:

- Manufacturers were excluded if their drugs are: (1) only used in clinical settings, (2) non-drug substances (such as vitamins), or (3) OTC drugs that are regulated as cosmetics or personal care products.
- Duplicate entries for companies with different divisions were excluded; however, subsidiary relationships have not yet been fully identified. Some companies on this list may be owned by the same parent company.
- The type of medicines sold by each manufacturer was added – those who sell both prescription (Rx) and over-the-counter (OTC); those who sell Rx only and those who sell OTC only. This information was obtained by comparison with the FDA National Drug Code database.
- Trade association membership was noted for member companies in PhRMA (pharmaceutical research & biotechnology), GPhA (generics), and CHPA (OTC/consumer healthcare).

Note that Cardinal's list does not include store brands for OTC drugs, such as Safeway Brand. But some manufacturers on this list make store brands. For example, Perrigo is the largest manufacturer of store brands, for WalMart, Walgreens, Kroger, and other stores with private label OTC drugs.

**In WA, Cardinal Health distributes medicines used in households from a total of 167 manufacturers:**

**63 Rx and OTC, 78 Rx only, and 26 OTC only.**

## Manufacturers of Prescription and Over-the-Counter Medicines Distributed in WA by Cardinal Health & Used in Households

	<b>Manufacturer</b> (CS) code indicates products include controlled substances	<b>Rx &amp; OTC</b>	<b>RX only</b>	<b>OTC only</b>	<b>Trade Association</b>
1	3M-CONSUMER HEALTH CARE			x	CHPA
2	AARON INDUSTRIES			x	CHPA
3	ABBOTT LABORATORIES		x		PhRMA
4	ACCORD HEALTHCARE INC. (CS)		x		
5	ACELLA PHARMACEUTICALS (CS)	x			
6	ACTAVIS (CS)	x			CHPA
7	ACTAVIS KADIAN LLC		x		
8	ACTIENT PHARMACEUTICALS LLC		x		
9	AKORN INC	x			
10	AKRIMAX PHARMACEUTICALS, LLC		x		
11	ALLERGAN INC	x			
12	ALVA - AMCO PHARMACAL COS., IN			x	CHPA

# Drug Companies Whose Products Are Distributed in Washington State by Cardinal Health (initial staff review)

	<b>Manufacturer</b> <small>(CS) code indicates products include controlled substances</small>	<b>Rx &amp; OTC</b>	<b>RX only</b>	<b>OTC only</b>	<b>Trade Association</b>
13	ALVOGEN INC		x		
14	AMERICAN HEALTH PACKAGING (CS)	x			
15	AMERICAN REGENT LABORATORIES		x		
16	AMGEN USA INC		x		PhRMA
17	AMNEAL PHARMACEUTICALS LLC (CS)	x			GPhA
18	APOTEX CORP (CS)	x			GPhA
19	APTALIS PHARMA US, INC		x		
20	ARBOR PHARMACEUTICALS INC		x		
21	ASCEND LABORATORIES (CS)		x		
22	ASTELLAS PHARMA / ASTELLAS PHARMA BRANDED		x		PhRMA
23	ASTRAZENECA		x		PhRMA
24	AUROBINDO PHARMA USA (CS)	x			
25	AVKARE INC. (CS)	x			
26	B BRAUN MEDICAL		x		
27	BAUSCH & LOMB (CS)	x			CHPA
28	BAYER HEALTHCARE LLC / BAYER HEALTHCARE PHARMACEUTICA	x			PhRMA
29	BECTON DICKINSON & CO			x	
30	BEDFORD LABORATORIES (CS)		x		
31	BIOCOMP PHARMA INC	x			
32	BLU PHARMACEUTICALS LLC		x		
33	BOCA PHARMACAL (CS)		x		
34	BOEHRINGER INGELHEIM	x			PhRMA/CH PA
35	BRECKENRIDGE PHARMACEUTICAL IN (CS)	x			
36	C B FLEET CO INC			x	
37	CAMBER PHARMACEUTICALS INC (CS)		x		
38	CARACO PHARMACEUTICAL (CS)	x			GPhA
39	CARDINAL HEALTH MED PROD & SER	x			
40	CARLSBAD TECHNOLOGY INC	x			
41	CAROLINA MEDICAL PRODUCTS CO		x		
42	CHATTEM LABORATORIES			x	CHPA
43	CHURCH & DWIGHT/ ARM & HAMMER			x	CHPA
44	COLOPLAST INC MENTOR	x			
45	COMBE INCORPORATED			x	CHPA
46	CONVATEC INC			x	
47	COREPHARMA LLC		x		
48	CORNERSTONE THERAPEUTICS INC		x		

# Drug Companies Whose Products Are Distributed in Washington State by Cardinal Health (initial staff review)

	<b>Manufacturer</b> (CS) code indicates products include controlled substances	<b>Rx &amp; OTC</b>	<b>RX only</b>	<b>OTC only</b>	<b>Trade Association</b>
49	CYPRESS PHARMA		X		
50	DAIICHI/SANKYO PHARMA, INC		X		PhRMA
51	DAVA PHARM INC		X		
52	DR REDDYS LABORATORIES INC (CS)		X		GPhA/CHPA
53	EISAI INC.		X		PhRMA
54	EMD SERONO, INC		X		PhRMA
55	ENDO LABORATORIES		X		PhRMA
56	ETHICON INC MEDSURGE		X		
57	FERNDAL LABORATORIES INC	X			
58	FERRING PHARM INC		X		
59	FOREST PHARMACEUTICALS		X		
60	FOUGERA PHARMACEUTICALS INC (CS)		X		GPhA
61	G & W LABORATORIES INC (CS)	X			GPhA
62	GALDERMA LABORATORIES INC	X			
63	GAVIS PHARMA	X			
64	GENENTECH USA		X		
65	GERITREX CORP			X	
66	GILEAD SCIENCES INC		X		
67	GLAXO SMITHKLINE / GLAXO SMITHKLINE CONSUMER	X			PhRMA/CHPA
68	GLENMARK GENERICS INC USA (CS)		X		GPhA
69	GLOBAL PHARMACEUTICAL / IMPAX LABS (branded)		X		
70	GLOBAL PHARMACEUTICAL (generic)		X		
71	GOLDEN STATE MEDICAL		X		
72	GREENSTONE LIMITED (CS)		X		
73	HARRIS PHARMACEUTICALS INC	X			
74	HERITAGE PHARMACEUTICALS INC (CS)		X		
75	HI - TECH PHARMACAL CO INC (CS)	X			GPhA
76	HISAMITSU AMERICA			X	CHPA
77	INTL MEDICATION SYS AMPHASTAR		X		
78	J & J SALES & LOGISTICS CO			X	PhRMA/CHPA
79	JAZZ PHARMA COMMERCIAL CORP		X		
80	KRAMER LABORATORIES INC			X	
81	KREMERS URBAN	X			GPhA
82	LANNETT CO INC (CS)		X		
83	LARKEN LABORATORIES, INC.	X			
84	LIL DRUG STORE PRODUCTS INC			X	CHPA



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	<b>Manufacturer</b> (CS) code indicates products include controlled substances	<b>Rx &amp; OTC</b>	<b>RX only</b>	<b>OTC only</b>	<b>Trade Association</b>
85	LILLY ELI & CO	x			PhRMA
86	LUNDBECK INC		x		PhRMA
87	LUPIN PHARM INC (CS)		x		
88	MAJESTIC DRUG CO INC			x	
89	MAJOR PHARMACEUTICALS (CS)	x			
90	MALLINCKRODT (CS)		x		
91	MARLEX PHARMACEUTICALS INC		x		
92	MCKESSON PACKAGING SERVICES	x			
93	MEDA PHARMACEUTICALS INC / MEDA CONSUMER HEALTHCARE INC	x			CHPA
94	MEDICIS PHARMACEUTICAL CORP	x			
95	MEDIMETRIKS PHARMACEUTICALS IN		x		
96	MEDLINE INDUSTRIES INC	x			
97	MEDTECH PRODUCTS INC			x	
98	MENTHOLATUM CO			x	
99	MERCK SHARP & DOHME CORP		x		PhRMA
100	MERZ PHARMACEUTICALS	x			
101	MISSION PHARMACAL CO		x		CHPA
102	MONARCH PHARMACEUTICALS		x		
103	MSD CONSUMER CARE			x	
104	MUTUAL PHARMACEUTICAL CO INC (CS)		x		
105	MYLAN PHARMACEUTICALS INC (CS) / MYLAN INSTITUTIONAL INC (CS)	x			GPhA
106	NEPHRON PHARMACEUTICALS CORP	x			
107	NOVARTIS PHARMACEUTICALS / NOVARTIS CONSUMER HEALTH	x			PhRMA/CH PA
108	NOVEN THERAPEUTICS LLC		x		
109	NOVO NORDISK INC	x			PhRMA
110	OHM LABS			x	
111	PACIFIC PHARMA		x		
112	PACK PHARMACEUTICALS LLC	x			
113	PADDOCK LABS INC (CS)	x			GPhA
114	PAR PHARM (CS)		x		GPhA
115	PATRIOT PHARMACEUTICALS LLC		x		
116	PERRIGO COMPANY	x			CHPA
117	PFIZER / PFIZER - WYETH CONSUMER HEALTHCARE	x			PhRMA/CH PA
118	PHARMACEUTICAL ASSOC (CS)	x			
119	PHARMADERM	x			

## Drug Companies Whose Products Are Distributed in Washington State by Cardinal Health (initial staff review)

	<b>Manufacturer</b> <small>(CS) code indicates products include controlled substances</small>	<b>Rx &amp; OTC</b>	<b>RX only</b>	<b>OTC only</b>	<b>Trade Association</b>
120	PRASCO LABS (CS)		X		
121	PRECISION DOSE INC (CS)	X			
122	PROCTER & GAMBLE CONSUMER	X			
123	PROPHASE LABS, INC			X	
124	PURDUE PHARMA LP (CS)	X			PhRMA
125	QUALITEST PROD INC (CS)	X			
126	RANBAXY LABORATORIES INC (CS) / RANBAXY PHARMACEUTICALS INC	X			GPhA
127	RECKITT BENCKISER INC			X	CHPA
128	REESE PHARMACEUTICALS INC			X	
129	RHODES PHARMACEUTICALS, L.P.		X		GPhA
130	RISING PHARMACEUTICAL INC (CS)	X			
131	ROUSES POINT PHARM, LLC		X		
132	ROXANE LABS INC (CS)	X			
133	SALIX PHARMACEUTICALS INC		X		
134	SANDOZ (CS)	X			GPhA
135	SANOFI - AVENTIS US LLC / SANOFI PASTEUR		X		PhRMA
136	SANTARUS, INC		X		
137	SAVAGE LABS INC		X		
138	SETON PHARMACEUTICALS LLC		X		
139	SHIONOGI PHARMACEUTICAL INC.		X		
140	SHIRE LLC. / SHIRE US INC		X		
141	SILARX PHARMA GENERICS	X			
142	SIMILASAN CORP			X	CHPA
143	SMITH & NEPHEW UNITED-WOUND CA			X	
144	SOLCO HEALTHCARE US LLC		X		
145	SUMMERS LABORATORIES INC.		X		
146	SUMMIT INDUSTRIAL			X	
147	SUNOVION PHARMACEUTICALS INC		X		PhRMA
148	SUNSTAR AMERICAS, INC		X		
149	TAKEDA PHARMACEUTICALS AMERICA		X		PhRMA
150	TARO PHARMA (CS)	X			CHPA/GPhA
151	TEVA PHARM USA (CS) / TEVA IVAX PHARMACEUTICALS	X			GPhA
152	TORRENT PHARMA INC	X			
153	U C B		X		
154	UNICHEM PHARMACEUTICAL USA	X			
155	UNITED EXCHANGE CORP			X	

# Drug Companies Whose Products Are Distributed in Washington State by Cardinal Health (initial staff review)

	<b>Manufacturer</b> <small>(CS) code indicates products include controlled substances</small>	<b>Rx &amp; OTC</b>	<b>RX only</b>	<b>OTC only</b>	<b>Trade Association</b>
156	UPSHER - SMITH LABS		x		GPhA
157	VALEANT PHARMACEUTICALS	x			CHPA
158	VERSAPHARM INC (CS)		x		GPhA
159	VIRTUS PHARMACEUTICAL LLC (CS)	x			
160	VISTAPHARM INC	x			
161	WARNER CHILCOTT		x		
162	WATSON LABS (CS)		x		GPhA
163	WEST WARD PHARMACEUTICAL	x			GPhA
164	WINTHROP US		x		
165	WOCKHARDT USA INC (CS)	x			
166	X-GEN PHARMACEUTICALS INC		x		
167	ZYDUS PHARMA USA INC	x			GPhA

## Manufacturers Excluded from Cardinal's List

The following manufacturers were removed from Cardinal's list because their products do not appear to include prescription or over-the-counter medicines used in households. Examples include manufacturers of the following products: drugs used only in a clinical setting, cosmetic and personal care products, products with natural ingredients, non-drug products, and products that could not be verified in the FDA National Drug Code database.

21ST CENTURY NUTRITIONAL PRODU  
A & D MEDICAL PRODUCTS  
ACTION BAG COMPANY  
ALBAAD USA, INC  
ALCON OPHTHALMIC PROD  
ALCON VISION CARE  
ALEX ORTHOPEDIC INC  
ALLIED PHARMACY PRODUCTS  
ALLISON MEDICAL  
AMG MEDICAL INC  
APEX-CAREX  
APLICARE INC  
APOTHECARY PRODUCTS INC  
APP / FRESENIUS KABI USA LLC  
ARKRAY USA INC  
ASO CORPORATION  
ATTENDS HEALTHCARE PRODUCTS IN  
AUROMEDICS PHARMA LLC  
B F ASCHER  
BARD UROLOGICAL DIV  
BASIC ORGANICS INC  
BASIC RESEARCH LLC  
BASIC VITAMINS  
BATTLE CREEK EQUIPMENT  
BAXA CORPORATION  
BAXTER ANESTHESIA & CRITICL CA

KERR GROUP INC  
KIMBERLY - CLARK CORPORATION  
KONSYL PHARMACEUTICALS INC  
LIBERTY PHARMACEUTICALS GDIST  
LIFESCAN INC  
LNK INTERNATIONAL INC  
MASON VITAMINS  
MC KEON PRODUCTS INC  
MEAD JOHNSON NUTRITIONALS  
MEDA ALAVEN PHARMACEUTICAL  
MEDEFIL INC  
MEDICOOL INC  
MEDISCA INC  
MEDISCA INC (CS)  
MEDQUIP INC  
MERCK HUMAN HEALTH DIVISION  
MHC MEDICAL PRODUCTS  
MICROLIFE USA, INC  
MOEN INCORPORATED  
MOLNLYCKE HEALTHCARE  
MONDELEZ SNACK COMPANY  
MUELLER SPORTS MEDICINE INC  
NATIONAL VITAMIN COMPANY INC  
NATROL INC  
NEILMED PRODUCTS, INC.  
NESTLE CLINICAL NUTRITION

# Drug Companies Whose Products Are Distributed in Washington State by Cardinal Health (initial staff review)

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BAXTER ANSTH & CRTCL CRE BRNDD  
BAXTER IV SYSTEMS  
BAXTER IV SYSTEMS (CS)  
BEAUMONT PRODUCTS INC  
BEIERSDORF INC  
BELL-HORN  
BESTSWEET  
BIC CORPORATION  
BLISTEX INC  
BOIRON BORNEMAN INC  
BRACCO - E Z EM  
BRACCO DIAGNOSTICS  
BRIGGS HEALTHCARE  
BRISTOL PRIMARY CARE PRODUCT  
BROADWAY INDUSTRIES  
BROWN MEDICAL INDUSTRIES  
BSN - MEDICAL  
C C A INDUSTRIES  
CADISTA PHARM INC (NCBNET)  
CADISTA PHARMA INC (CS NCB NE  
CARA INCORPORATED  
CAREX HEALTH BRANDS  
CARMA LABORATORIES INC  
CASHCO DISTRIBUTORS INC  
CLEANLIFE PRODUCTS  
COLGATE - PALMOLIVE COMPANY  
COLGATE ORAL PHARMACEUTICALS R  
CONTINENTAL FRAGRANCES LTD  
COVIDIEN HEALTHCARE  
COVIS PHARMACEUTICALS INC  
CUTIS PHARMA INC  
DEL - RAY LABS INC  
DERMA RITE INDUSTRIES  
DEVILBISS HEALTHCARE  
DIAL CORPORATION  
DOME INDUSTRIES  
DR FRESH INC  
DSE HEALTHCARE SOLUTIONS LLC  
DYNAREX CORP  
E T BROWNE DRUG CO INC  
ELKAY PLASTICS CO  
EMERSON HEALTHCARE  
ENERGIZER GLOBAL HEADQUARTERS  
ENERGIZER PERSONAL CARE  
ENZYMATIC THERAPY INC  
ESSENTIAL MEDICAL  
EXCELSIOR MED CORP  
FALLENE LTD  
FARLEYS & SATHERS CANDY (KINRA  
FIRST QUALITY PRODUCTS INC  
FRENCH TRANSIT LTD  
FRUIT OF THE EARTH  
GARNIER  
GE HEALTHCARE  
GENENTECH/ROCHE LABORATORIES I  
GENUINE VIRGIN ALOE DBA TRIDER  
GERI CARE PHARM  
GLENWOOD L L C  
GOLDEN FARM CANDIES  
GSK - AIR  
HEALTH CARE PRODUCTS

NEWHALL LABS  
NIPRO DIAGNOSTICS INC  
NORTHWEST NATURAL PRODUCTS  
NUMARK LAB INC  
NUTRICIA NORTH AMERICA  
NVP ACTION BAG COMPANY  
NVP APP / FRESENIUS KABI USA L  
NVP BEN VENUE LABORATORIES  
NVP GE HEALTHCARE  
NVP PFIZER INJECTABLE  
NVP SANDOZ (GENEVA)  
OAKHURST COMPANY  
OMRON HEALTHCARE  
ONSET DERMATOLOGICS LLC  
ONSET DERMATOLOGICS LLC TRIAX  
OWEN MUMFORD  
PACIFIC WORLD CORP  
PARI RESPIRATORY EQUIPMENT INC  
PEDIFIX  
PERFECTA PRODUCTS INC.  
PERIO PRODUCTS  
PERSON & COVEY  
PHARMACEUTICALS SPECIALTIES  
PHARMACISTS ULTIMATE HEALTH  
PHARMAVITE CORPORATION  
PL DEVELOPMENTS  
PLUS PHARMA INC  
PRECISION FOODS INC  
PREMIER BRANDS OF AMERICA INC  
PRO FOOT CARE PRODUCTS  
PROMOTIONS UNLIMITED  
PRUGEN INC (CS)  
QUINNOVA PHARMACEUTICALS  
RARITAN PHARMACEUTICALS  
RD PLASTICS CO INC  
RESPIRONICS INC  
REVLON INC  
REXAM  
RICOLA INC  
ROCHE DIAGNOSTICS  
SABONA OF LONDON UNLIMITED INC  
SAGENT  
SAGENT PHARMACEUTICALS, INC - C  
SALK COMPANY INC.  
SCA PERSONAL CARE  
SCHIFF NUTRITION  
SCOTT SPECIALTIES INC  
SHAMROCK MANUFACTURING COMPANY  
SHEPARD MEDICAL PRODUCTS, INC  
SPENCO MEDICAL CORP  
STANDER INC  
STEADMED MEDICAL  
STRATUS PHARM (CS)  
SUN & SKIN CARE RESEARCH, LLC  
SUNBEAM PRODUCTS INC  
SURGICAL APPLIANCE INDUSTRIES  
TARO PHARMACEUTICALS USA INC  
TEC LABORATORIES  
TENDER CORPORATION  
TRI STATE DISTRIBUTION  
TRIGEN LABS INC (CS)

## Drug Companies Whose Products Are Distributed in Washington State by Cardinal Health (initial staff review)

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HEALTH ENTERPRISES INC  
HEALTHPOINT BIOTHERAPEUTICS  
HIGH PERFORMANCE FITNESS INC  
HIGH RIDGE BRANDS CO  
HILLSIDE CANDY  
HOLLISTER INCORPORATED  
HOMEDICS INC  
HOSPIRA (CS)  
HOSPIRA CONTROL  
HOSPIRA WORLDWIDE INC  
HUMCO HOLDING GROUP  
HYGENIC PERFORMANCE HEALTH  
HYLANDS INC  
IDELLE LABS, LTD  
I-HEALTH, INC.  
ILEX CONSUMER PRODUCTS GROUP L  
INTERNATIONAL VITAMIN CORP  
IOVATE HEALTH SCIENCES USA INC  
IRWIN NATURALS  
J H P PHARMACEUTICALS  
J H P PHARMACEUTICALS (GENERIC)  
J O M PHARM (SCHEDULE)  
J O M PHARMACEUTICAL SERVICES  
K V K TECH INC  
K V K TECH INC (CS)  
KAO USA INC  
KAZ INC

TRONEX COMPANY  
TWIN LABORATORIES  
TWT DISTRIBUTING INC  
U S COTTON INC  
ULTI MED INC  
UNILEVER  
UPSHER - SMITH LABS INC - BRAN  
UPSHER SMITH LABS INC - GENERI  
US NUTRITION  
VERIDIAN HEALTHCARE LLC  
VI JON INC  
W F YOUNG INC  
W.E. BASSETT CO.  
WATERPIK TECHNOLOGIES INC  
WATKINS INCORPORATED  
WEST WARD INJECTIBLE  
WEST WARD PHARMACEUTICAL CORP  
WEST-WARD PHARMACEUTICAL (INJ)  
WINDMILL HEALTH PRODUCTS LLC  
ZEWA INC

The following manufacturers were also removed as a duplicate listing of a company which is included in the list of manufacturers of Rx and OTC medicines sold in WA state and used in households.

ABBOTT - LUPRON  
ABBOTT DIABETES CARE SALES COR  
ABBOTT MEDICAL OPTICS INC  
ABBOTT NUTRITION  
AKORN OPHTHALMICS  
BAUSCH & LOMB / SOFLENS  
BAYER HEALTHCARE DIABETES CARE  
BECTON DICKINSON CONS  
BOEHRINGER INGELHEIM CONSUMER  
DAVA PHARM INC (NCBNET)  
J & J TYLENOL/MOTRIN OTHER INS  
MALLINCKRODT BRANDED  
MALLINCKRODT MEDICAL INC  
MCKESSON SPECIALTY LLC  
MYLAN - BRAND  
MYLAN INSTITUTIONAL INC (CS)  
MYLAN INSTITUTIONAL LLC  
MYLAN SPECIALTY L P  
NOVARTIS PHARM - AIR

PERRIGO DIABETES CARE  
PERRIGO PHARM CLAY PARK OTC  
PERRIGO PHARM CLAY PARK OTC -  
PERRIGO PHARM CLAY PARK RX  
PERRIGO PHARM CLAY PARK RX - C  
PFIZER - CD  
PFIZER INJECTABLE  
PFIZER USPG  
PROCTER & GAMBLE - FEM CARE  
PROCTER & GAMBLE SPCLTY BATTER  
PURDUE PRODUCTS LP - OTC  
RECKITT BENCKISER  
TEVA / IVAX LABS INC (BRAND)  
VALEANT PHARMACEUTICALS - CD  
WATSON - OTC  
WATSON LABS - BRAND  
WATSON RUGBY LAB (CS)  
WATSON RUGBY LABS  
ZYDUS PHARMA USA INC (NCB NET)

This handbook to over-the-counter (OTC) drugs is from the Consumer Healthcare Products Association. It lists categories of OTC drugs, and their active ingredients.

Mark-up has been added to indicate OTC drugs that are also regulated as cosmetics, i.e. products "for cleansing, beautifying, promoting attractiveness, or altering the appearance." These OTC/cosmetic products are typically excluded from medicine take-back programs.

# your<sup>+</sup>health AT HAND book



## Guide to OTC Active Ingredients in the United States

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## Your Health at Hand Book: Guide to OTC Active Ingredients in the United States

October 2010

Published annually by:  
Consumer Healthcare Products Association  
900 19th Street, NW, Suite 700, Washington, DC 20006  
[chpa-info.org](http://chpa-info.org) | [OTCsafety.org](http://OTCsafety.org)

Corrections and updates should be sent to CHPA via e-mail to [Mary.McDonald@chpa-info.org](mailto:Mary.McDonald@chpa-info.org).

# Regulatory Background and Glossary

## Regulatory Routes for the Marketing of Over-the-Counter (OTC) Drug Products in the United States

OTC drug products can be marketed under the authority of an approved product-specific new drug application (NDA), abbreviated NDA (ANDA), or under an OTC drug monograph. Unlike NDAs which are based on drug products, monographs specify the active ingredients that can be contained within OTC drug products. In addition to specifying the active ingredients, the OTC monographs contain information regarding the permitted concentrations of active ingredients, dosage limits, indications, and other requirements for legal marketing under monograph status. In order to be eligible for an OTC drug monograph, it is FDA's policy (with limited exceptions) that an active ingredient had to be marketed as an OTC medicine at the inception of the OTC Drug Review on May 11, 1972, later extended to December 4, 1975, or before. OTC drug products are marketed under a final monograph (FM), which is a regulation, or a tentative final monograph (TFM), which represents FDA's current position on the requirements for safe and effective labeling, formulation, and marketing of a product. In addition, it is FDA's practice (with limited exceptions) to permit the continued marketing of active ingredients or certain combinations during the pendency of an FM or TFM on condition that these ingredients were commercially marketed within OTC products prior to December 4, 1975, and that

such products do not constitute a hazard to health. This document focuses on permitted OTC active ingredients. Users of this document are invited to consult the pertinent *Federal Register* notices and NDAs about permitted concentrations of active ingredients, dosage limits, indications, and other requirements for legal marketing under monograph status.

## Product Categories

The *Your Health at Hand Book* follows FDA's classification of active ingredients and their allocation to product categories. However, since active ingredients listed in the product category "Dermal Antifungals," for example, can have an anti-dandruff indication without being mentioned in the product category of "Dandruff Drug Products," we used the FDA's product category organization rather than cross-referencing all possible indications.



# Active Ingredients

The tables provide the names of the active moieties of ingredients which are used in OTC drug products in the United States under one of the following regulatory status:

- 1. New drug application (NDA). The date of the first NDA OTC approval of the ingredient, ingredient combination, extended release form, or new indication is provided. However, the tables do not contain subsequent approvals of generic versions; other strengths, concentrations, formulations, or uses in subpopulations (e.g. children); or salts, esters, or other derivatives of the active ingredient.
- 2. Category I ingredients (generally recognized as safe and effective for the claimed therapeutic indication) contained in a tentative final monograph (TFM) or a final monograph (FM). The date of issuance of the monograph is provided in brackets.
- 3. Category III ingredients (insufficient data available to permit final classification) contained in marketed products. Such ingredients are referred to as "FM pending."

Only where it was deemed as essential for the understanding of the active ingredient information, the tables include the names of salts, esters, or other derivatives of the active moieties.

# Brand Examples

Sources used for identifying brand examples were the *PDR for Nonprescription Drugs, Dietary Supplements, and Herbs* (21 edition, 2010) and the web page of the largest Internet retailer in the United States, drugstore.com (accessed August 2010). The purpose of providing brand examples is to reflect the use of active ingredients rather than providing an inclusive list of all brands on the market. These brand examples are not listed in any particular order.

## Date of NDA OTC Approval

The *Orange Book* and various other FDA sources were used to identify and verify the information concerning NDA approval dates.

**Glossary of abbreviations:**  
  
ANPR = Advance notice of proposed rulemaking  
ER = Extended release  
FM = Final monograph  
NDA = New drug application  
NPR = Notice of proposed rulemaking  
TFM = Tentative final monograph

A. Internal (Oral) Analgesics

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Internal Analgesics	OTC Monograph Single Ingredients	TFM (Nov. 16, 1988)	aspirin	BAYER ASPIRIN, ECOTRIN, BUFFERIN
			acetaminophen	TYLENOL
			carbaspirin	
			salicylate and its salts (choline, magnesium, or sodium)	DOAN'S, PERCOGESIC MAXIMUM STRENGTH magnesium salicylate
	OTC Monograph Combinations	TFM (Nov. 16, 1988)	acetaminophen with other analgesics	GOODY'S BODY PAIN acetaminophen/aspirin
			acetaminophen with antacids	
			aspirin with antacids	ALKA SELTZER EXTRA STRENGTH aspirin/citric acid/sodium bicarbonate
			combinations with cough and cold ingredients	See B. Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Products
			combinations with diuretics	see L. Menstrual Products
		Proposed TFM amendment (Dec. 24, 1991)	any analgesic with caffeine	EXCEDRIN EXTRA STRENGTH, ANACIN HEADACHE, VANQUISH acetaminophen/aspirin/caffeine
	NDA	prior Jan. 1, 1982	acetaminophen suppositories	FEVERALL
		May 18, 1984	ibuprofen	ADVIL, MOTRIN
		June 8, 1984	acetaminophen ER	TYLENOL ARTHRITIS PAIN
		Sept. 19, 1989	ibuprofen/pseudoephedrine	ADVIL COLD & SINUS
		Jan. 11, 1994	naproxen	ALEVE
		Oct. 6, 1995	ketoprofen	
		Jan. 14, 1998	aspirin/acetaminophen/caffeine for migraine	EXCEDRIN MIGRAINE
		Nov. 29, 1999	naproxen/pseudoephedrine	ALEVE-D SINUS & COLD
		Feb. 25, 2000	ibuprofen for migraine	MOTRIN MIGRAINE, ADVIL MIGRAINE
		Oct. 18, 2001	aspirin for migraine	BAYER ASPIRIN MIGRAINE
		Dec. 19, 2002	ibuprofen/pseudoephedrine/chlorpheniramine	ADVIL ALLERGY SINUS

## B. Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Products

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Oral Antitussives	OTC Monograph Single Ingredients	FM (Aug. 12, 1987)	chlophedianol	
			codeine	
			dextromethorphan	ROBITUSSIN DM, SUCRETS DM, HOLD DM, VICKS DAYQUIL
		FM (June 3, 1994)	diphenhydramine	
	NDA	Oct. 8, 1982	dextromethorphan (ER)	DELSYM ER
		April 29, 2004	dextromethorphan/guaifenesin (ER)	MUCINEX DM ER
Oral Nasal Decongestants	OTC Monograph Single Ingredients	FM (Aug. 23, 1994)	pseudoephedrine	SUDAFED
			phenylephrine	SUDAFED PE
	NDA	Sept. 13, 1982	pseudoephedrine (ER12 hours)	SUDAFED 12 HOURS
		Dec. 15, 1992	pseudoephedrine (ER 24 hours)	
Oral First-Generation Antihistamines	OTC Monograph Single Ingredients	FM (Dec. 9, 1992)	brompheniramine, chlorcyclizine, chlorpheniramine, dexbrompheniramine, dexchlorpheniramine, diphenhydramine, phenindamine, pheniramine, pyrilamine, thonzylamine, triprolidine	BENADRYL ALLERGY diphenhydramine
				CHLOR-TRIMETON chlorpheniramine
		FM (Jan. 28, 1994)	doxylamine	
	NDA	prior Jan. 1, 1982	chlorpheniramine (ER)	CHLOR-TRIMETON 12 HOURS
		prior Jan. 1, 1982	chlorpheniramine/pseudoephedrine (ER)	
		Sept. 13, 1982	dexbrompheniramine/pseudoephedrine (ER)	DRIXORAL
		May 22, 1987	dexbrompheniramine/pseudoephedrine/acetaminophen ER	DRIXORAL PLUS
		Aug. 21, 1992	clemastine	TAVIST
		March 1, 2001	clemastine/pseudoephedrine/acetaminophen	TAVIST ALLERGY SINUS HEADACHE
Oral Second-Generation Antihistamines	NDA	Nov. 27, 2002	loratadine	CLARITIN, ALAVERT
		Nov. 27, 2002	loratadine/pseudoephedrine (ER)	CLARITIN D 24 HOURS
		Nov. 16, 2007	cetirizine	ZYRTEC
		Nov. 9, 2007	cetirizine/pseudoephedrine	ZYRTEC D
Oral Expectorants	OTC Monograph Single Ingredients	FM (Feb. 28, 1989)	guaifenesin	MUCINEX, LITTLE COLDS MUCUS RELIEF
	NDA	July 12, 2002	guaifenesin (ER)	MUCINEX ER
		June 22, 2004	guaifenesin/pseudoephedrine (ER)	MUCINEX D ER

continued next page

B. Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Products

continued

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Oral Cough and Cold Active Ingredients Combinations	OTC Monograph Combinations	FM (Dec. 23, 2002)	combinations of antitussive, decongestant, antihistamine, expectorant, analgesic, and oral demulcent active ingredients	TRIAMINIC DAYTIME phenylephrine/dextromethorphan
				DIMETAPP NIGHTTIME phenylephrine/diphenhydramine
				TYLENOL COUGH DAYTIME phenylephrine/ dextromethorphan/ acetaminophen
				VICKS NYQUIL VITAMIN C, CORICIDIN HBP NIGHTTIME doxylamine/ dextromethorphan/ acetaminophen
				THERAFLU COLD & COUGH pheniramine/phenylephrine/ dextromethorphan
				BUCKLEY'S CHEST CONGESTION guaifenesin/menthol
Bronchodilators	OTC Monograph Single Ingredients	FM (Oct. 2, 1986)	ephedrine, racephedrine	
			epinephrine, racepinephrine	PRIMATENE MIST
	OTC Monograph Oral Combinations	FM pending	ephedrine/guaifenesin	PRIMATENE TABLETS, BRONKAID
Topical Antitussives	OTC Monograph Single Ingredients	FM (Aug. 12, 1987)	camphor	VICKS VAPOSTEAM
			menthol	FISHERMAN'S FRIEND
	OTC Monograph Combinations	FM (Dec. 23, 2002)	camphor/menthol	
			camphor/menthol/eucalyptus oil	VICKS VAPORUB, MENTHOLATUM CHEST RUB
Topical Nasal Decongestants	OTC Monograph Single Ingredients	FM (Aug. 23, 1994)	ephedrine	
			naphazoline	
			oxymetazoline	AFRIN, VICKS SINEX, SUDAFED OM, NOSTRILLA, ZICAM SINUS RELIEF
			phenylephrine	NEO-SYNEPHRINE, LITTLE NOSES DECONGESTANT, 4-WAY
			propylhexedrine	BENZEDREX
			xylometazoline	
Topical Nasal Allergy Symptom Controllers	NDA	Jan. 6, 1997	cromolyn sodium	NASALCROM

## C. Nighttime Sleep Aids

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Nighttime Sleep-Aids	OTC Monograph Single Ingredients	FM (Feb. 14, 1989)	diphenhydramine	UNISOM, SOMINEX, COMPOZ
	OTC Monograph Combinations	FM pending	aspirin/diphenhydramine	BAYER ASPIRIN PM
			acetaminophen/diphenhydramine	TYLENOL PM
	NDA	Oct. 18, 1978	doxylamine	UNISOM
			ibuprofen/diphenhydramine	ADVIL PM

## D. Stimulants (Caffeine)

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Stimulants	OTC Monograph Single Ingredients	FM (Feb. 29, 1988)	caffeine	NODOZ, VIVARIN

E. Gastrointestinals

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Acid reducers - Antacids	OTC Monograph Single Ingredients	FM (June 4, 1974)	aluminum-based antacids, bicarbonate-based antacids, bismuth-based antacids, calcium (carbonate or phosphate), citrate ion as citric acid or salt, glycine, magnesium-based antacids, milk solids dried, phosphate-based antacids, potassium-based antacids, sodium-based antacids, silicates, tartaric acid or its salts	PEPTO-BISMOL ORIGINAL bismuth subsalicylate
				TUMS, PEPTO-BISMOL CHILDREN'S calcium carbonate
				PHILLIPS ORIGINAL magnesium hydroxide
	OTC Monograph Combinations	FM (June 4, 1974)	combinations of antacids	ALKA SELTZER ANTACID RELIEF citric acid/sodium bicarbonate/ potassium bicarbonate
				MYLANTA aluminum hydroxide / magnesium hydroxide
				ROLAIDS calcium carbonate/magnesium hydroxide
				GAVISCON aluminum hydroxide/magnesium carbonate
			combinations with any nonantacid laxative	
			combinations with analgesics	See A. Internal Analgesics
			combinations with anti-flatulents	MAALOX CHILDREN'S calcium carbonate /simethicone
				MAALOX, GELUSIL aluminum hydroxide/magnesium hydroxide/simethicone
Acid reducers - H <sub>2</sub> - Antagonists	NDA	April 28, 1995	famotidine	PEPCID
		June 19, 1995	cimetidine	TAGAMET
		Dec. 19, 1995	ranitidine	ZANTAC
		May 9, 1996	nizatidine	
		Oct. 17, 2000	famotidine/calcium carbonate/ magnesium hydroxide	PEPCID COMPLETE
Acid reducers - Proton Pump Inhibitors	NDA	June 20, 2003	omeprazole	PRILOSEC OTC
		May 18, 2009	lansoprazole	PREVACID
		Dec. 1, 2009	omeprazole/sodium bicarbonate	ZEGERID OTC
Antiflatulents	OTC Monograph Single Ingredients	FM (April 6, 1974)	simethicone	GAS-EX, LITTLE TUMMY'S GAS
	OTC Monograph Combinations	FM (April 6, 1974)	combinations with antacids	see above Antacids - combinations with antiflatulents

## E. Gastrointestinals

continued

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Antidiarrheals	OTC Monograph Single Ingredients	FM (April 17, 2003)	bismuth subsalicylate	
			kaolin	
	NDA	March 3, 1988	loperamide	IMODIUM
		June 26, 1997	loperamide/simethicone	IMODIUM MULTI-SYMPTOM RELIEF
Bulk-Forming Laxatives	OTC Monograph Single Ingredients	TFM (Jan. 15, 1985)	polycarbophil	FIBERCON, EQUALACTIN
			psyllium ingredients	METAMUCIL
			bran	
			cellulose	CITRUCEL methylcellulose
			karaya	
			malt soup extract	
Hyperosmotic Laxatives	OTC Monograph Single Ingredients	TFM (Jan. 15, 1985)	glycerin	FLEET LIQUID GLYCERIN
			sorbitol	
	NDA	October 6, 2006	polyethylene glycol 3350	MIRALAX
Lubricants	OTC Monograph Single Ingredients	TFM (Jan. 15, 1985)	mineral oil	FLEET MINERAL OIL ENEMA
Saline Laxatives	OTC Monograph Single Ingredients	TFM (Jan. 15, 1985)	magnesium hydroxide	
			sodium phosphate, sodium biphosphate	FLEET PEDIA-LAX ENEMA
			magnesium citrate, magnesium sulfate	
Stimulant Laxatives	OTC Monograph Single Ingredients	TFM (Jan. 15, 1985)	bisacodyl	DULCOLAX, ALOPHEN, FLEET STIMULANT LAXATIVE, CORRECTOL
			sennosides	SENOKOT, EX-LAX, FLETCHER'S LAXATIVE
			castor oil	
			dehydrocholic acid	
Stool Softeners	OTC Monograph Single Ingredients	TFM (Sept. 2, 2003)	docusate	COLACE, PHILLIPS STOOL SOFTENER
Carbon Dioxide- Releasing Laxatives	OTC Monograph Single Ingredients	TFM (Jan. 15, 1985)	carbon dioxide released from combined sodium biphosphate anhydrous, sodium acid pyrophosphate and sodium bicarbonate	
			carbon dioxide released from combined sodium bicarbonate and potassium bitartrate	
Laxative Active Ingredients Combinations	OTC Monograph Combinations	TFM (Jan. 15, 1985)	combinations of laxatives	
				PERI-COLACE sennosides/docusate

continued next page

E. Gastrointestinals

continued

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Antiemetics	OTC Monograph Single Ingredients	FM (April 30, 1987)	cyclizine	BONINE FOR CHILDREN, MAREZINE
			dimenhydrinate	DRAMAMINE ORIGINAL, TRIPTONE
			diphenhydramine	
			meclizine	BONINE, ANTIVERT
Anthelmintics	OTC Monograph Single Ingredients	FM (Aug. 1, 1986)	pyrantel pamoate	PIN-X, PRONTO
Poison Treatment	OTC Monograph Single Ingredients	TFM (Jan. 15, 1985)	ipecac syrup	
			activated charcoal	CHARCOCAPS

F. Analgesics, Anesthetics, Counterirritants, & Antipruritics (External Analgesics)

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Amine and Caine'-Type Ingredients (Local Anesthetics)	OTC Monograph Single Ingredients	TFM (Feb. 8, 1983)	benzocaine, butamben picrate, dibucaine, dimethisoquin, dyclonine, lidocaine, pramoxine, tetracaine	SOLARCAINE lidocaine
				SCALPICIN WIPES pramoxine
				ORAJEL COLD SORE dyclonine
Alcohols and Ketones	OTC Monograph Single Ingredients	TFM (Feb. 8, 1983)	benzyl alcohol, camphor, camphorated metacresol, juniper tar, menthol, phenol, phenolate sodium, resorcinol	
Antihistamines	OTC Monograph Single Ingredients	TFM (Feb. 8, 1983)	diphenhydramine	
			tripelennamine	
Hydrocortisone Preparations	OTC Monograph Single Ingredients	TFM (Feb. 8, 1983)	hydrocortisone	CORTIZONE, CORTAID, ITCH-X HYDROCORTIFOAM
Irritants That Produce Redness	OTC Monograph Single Ingredients	TFM (Feb. 8, 1983)	allyl isothiocyanate, ammonia, methyl salicylate, turpentine oil	AFTER BITE ammonia
		FM pending	trolamine salicylate	ASPERCREME, MOBISYL
Irritants That Produce Cooling Sensation	OTC Monograph Single Ingredients	TFM (Feb. 8, 1983)	camphor	BLUE STAR
			menthol	ICY HOT, ABSORBINE, BENGAY, STOPAIN
Irritants That Produce Vasodilation	OTC Monograph Single Ingredients	TFM (Feb. 8, 1983)	histamine dihydrochloride	
			methyl nicotinate	
Irritants That Don't Produce Redness	OTC Monograph Single Ingredients	TFM (Feb. 8, 1983)	capsaicin	CAPZASIN, ZOSTRIX



F. Analgesics, Anesthetics, Counterirritants, & Antipruritics (External Analgesics)

continued

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
External Analgesics Combinations	OTC Monograph Combinations	TFM (Feb. 8, 1983)	combinations of external analgesic active ingredients, combinations with skin protectant and topical antimicrobial active ingredients	<a href="#">BENADRYL GEL</a> diphenhydramine/zinc acetate
				<a href="#">BACTINE</a> lidocaine/benzalkonium chloride
				<a href="#">IVAREST POISON IVY</a> diphenhydramine/calamine/benzyl alcohol
				<a href="#">LANACANE</a> benzocaine/benzethonium chloride
				<a href="#">VAGISIL ANTI-ITCH</a> benzocaine/resorcinol
				<a href="#">THERAGESIC, MENTHOLATUM DEEP HEATING</a> benzocaine/resorcinol
				<a href="#">SATOGESIC</a> methyl salicylate/camphor/menthol
				<a href="#">BOROLEUM</a> camphor/menthol/white petrolatum
	NDA	Feb. 20, 2008	methyl salicylate/menthol	<a href="#">SALONPAS PATCH</a>

highlighted products are excluded as OTC/cosmetics

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Skin Protectants	OTC Monograph Single Ingredients	FM (June 4, 2003)	allantoin, aluminum hydroxide gel, calamine, cocoa butter, cod liver oil, colloidal oatmeal, dimethicone, glycerin, hard fat, kaolin, lanolin, mineral oil, petrolatum, sodium bicarbonate, topical starch, white petrolatum, zinc acetate, zinc carbonate, zinc oxide	AVEENO BABY dimethicone
				JOHNSON'S BABY, BALMEX DIAPER RASH zinc oxide
				DESITIN MULTI-PURPOSE white petrolatum
Skin Protectants Astringents	OTC Monograph Single Ingredients	FM (June 4, 2003)	aluminum acetate, aluminum sulfate, witch hazel	
Skin Protectants Combinations	OTC Monograph Combinations	FM (June 4, 2003)	combinations with external analgesic, first aid antiseptic, and sunscreen active ingredients	GOLD BOND MEDICATED BODY LOTION zinc oxide/menthol
				BLISTEX MEDICATED LIP BALM dimethicone/oxybenzone/padimate
				PALMER'S MEDICATED LIP BUTTER petrolatum/camphor/menthol
				CHAPSTICK MEDICATED LIP BALM petrolatum/camphor/menthol/phenol
				SOFTLIPS LIP PROTECTANT dimethicone/octinoxate/oxybenzone/ octisalate
		FM (March 6, 2009)	aluminum sulfate tetradecahydrate combined with calcium acetate monohydrate in powder or tablet form to provide an aluminum acetate solution	
Cold Sore Treatment Combinations	OTC Monograph Combinations	NPR (Jan. 1, 1990)	combinations of skin protectant with external analgesic active ingredients	ANBESOL COLD SORE allantoin/camphor/benzocaine/white petrolatum
				CARMEX menthol/camphor/alum/salicylic acid/ phenol
Dandruff, Seborrheic Dermatitis, and Psoriasis Drug Products	NDA	July 25, 2000	docosanol	ABREVA
	OTC Monograph Single Ingredients	FM (Dec. 4, 1991)	coal tar	NEUTROGENA T/GEL ORIGINAL, PSORIASIN
			pyrithione zinc	HEAD & SHOULDERS, ZINCON
			salicylic acid	DENOREX, DERMAREST PSORIASIS
			selenium sulfide	SELSUN
			sulfur	
	OTC Monograph Combinations	FM (Dec. 4, 1991)	salicylic acid/sulfur	ALA SEB
		FM (March 6, 2007)	coal tar/menthol	

## G. Skin Treatment Products

continued

highlighted products are excluded as OTC/cosmetics

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Acne Products	OTC Monograph Single Ingredients	FM (Aug. 16, 1991)	resorcinol	
			salicylic acid	CLEARASIL, CLEAN & CLEAR, PANOXYL, OXY, STRIDEX, PHISODERM
			sulfur	
	OTC Monograph Combinations	FM (March 4, 2010)	benzoyl peroxide	CLEARASIL, CLEAN & CLEAR, PANOXYL, OXY
	OTC Monograph Combinations	FM (Aug. 16, 1991)	resorcinol/sulfur	ACNOMEL
Corn, Callus, and Wart Removers	OTC Monograph Single Ingredients	FM (Aug. 14, 1990)	salicylic acid	DR.SCHOLL'S, WART-OFF, COMPOUND W
Poison Ivy, Oak & Sumac Rash Prevention	NDA	Aug. 26, 1997	bentoquatam	IVY BLOCK
Antiperspirants	OTC Monograph Single Ingredients	FM (Jun. 9, 2003)	aluminum chlorohydrate, aluminum chlorohydrax, aluminum zirconium, and derivatives thereof	SPEED STICK, GILLETTE, AXE
Skin Bleaching Products	OTC Monograph Single Ingredients	TFM (Jan. 15, 1985)	hydroquinone	PALMER'S, AMBI
Dermal Antifungals	OTC Monograph Single Ingredients	FM (Sept. 23, 1993)	clioquinol	
			haloprogin	
			miconazole	DESENEX, CRUEX
			povidone-iodine	
			tolnaftate	TINACTIN, TING, ODOR-EATERS, DR.SCHOLL'S
			undecylenic acid and its salts (calcium, copper, and zinc)	
	NDA	FM (Feb. 8, 2002)	clotrimazole	MYCELEX
		Oct. 10, 1997	ketoconazole	NIZORAL
		March 9, 1999	terbinafine	LAMISIL
		Dec. 7, 2001	butenafine	LOTRIMIN ULTRA
Pediculicides	OTC Monograph Combinations	FM (Dec. 14, 1993)	pyrethrum extract/piperonyl butoxide	RID, PRONTO
	NDA	May 2, 1990	permethrin	PERMETHRIN, NIX

continued next page

highlighted products are excluded as OTC/cosmetics

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Sunscreens	OTC Monograph Single Ingredients	FM (May 21, 1999)	aminobenzoic acid (PABA), avobenzene, cinoxate, dioxybenzone, homosalate, menthyl anthranilate (meradimate), octocrylene, octyl methoxy-cinnamate (octinoxate), octyl salicylate (octisalate), oxybenzone, padimate O, phenylbenzimidazole sulfonic acid (ensulozide), sulisobenzene, titanium dioxide, trolamine salicylate, zinc oxide	
	OTC Monograph Combinations	FM (May 21, 1999)	combinations of sunscreen active ingredients	BAIN SOLEIL, COPPERTONE, BULL FROG, NEUTROGENA
	NDA	July 21, 2006	ecamsule/avobenzene/octocrylene	ANTHELIOS SX

Note on band-aids and bandages: FDA regulates these as devices, not as drugs. Medicated bandages, ie that include antibiotics, may be regulated as OTC combination products (drug/device) and could be specifically excluded if desired.

H. Hair Loss Products

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Hair Grower	NDA	Feb. 9, 1996	minoxidil	ROGAINE

## I. Topical Antiseptics and Antibiotics

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Healthcare Antiseptics (applied topically to the skin to prevent infection or cross contamination)	OTC Monograph Single Ingredients	TFM (June 17, 1994)	Handwash products: alcohol, povidone-iodine	<a href="#">PURELL</a> alcohol
			Patient preoperative skin preparations: alcohol, iodine tincture, isopropyl alcohol, povidone-iodine	
			Surgical hand scrubs: alcohol, povidone-iodine	
		FM pending	triclosan (handwash, patient preoperative preparation)	<a href="#">PALMOLIVE ULTRA, DIAL</a>
			triclocarban (all uses)	<a href="#">CUTICURA</a>
	NDA	Sept. 17, 1976	chlorhexidine gluconate	<a href="#">HIBICLENS, BETASEPT</a>
		Nov. 29, 1985	povidone-iodine (sponge)	<a href="#">E-Z SCRUB 201</a>
First Aid Antiseptics (to prevent infection in wounds, scrapes, and burns)	OTC Monograph Single Ingredients	TFM (July 22, 1991)	alcohol, benzalkonium chloride, benzethonium chloride, camphorated metacresol, camphorated phenol in light mineral oil vehicle, eucalyptol, hexylresorcinol, hydrogen peroxide, iodine tincture, iodine topical solution, isopropyl alcohol, menthol, methylbenzethonium chloride, methyl salicylate, phenol, povidone-iodine, thymol	<a href="#">BETADINE</a> povidone-iodine
				<a href="#">IODEX</a> iodine
		FM pending	chloroxylenol	
	OTC Monograph Combinations	TFM (July 22, 1991)	combination of alcohol, eucalyptol, menthol, methyl salicylate, and thymol	
			combinations with external analgesics	<a href="#">LANACANE FIRST AID</a> benzethonium chloride/benzocaine
				<a href="#">FOILLE</a> chloroxylenol/benzocaine
				<a href="#">GOLD BOND FIRST AID</a> benzethonium chloride/menthol
				<a href="#">BACTINE FIRST AID</a> benzalkonium chloride/lidocaine
			combinations with skin protectants	
First Aid Antibiotics	OTC Monograph Single Ingredients	FM (Dec. 11, 1987)	bacitracin, bacitracin zinc, chlortetracycline, neomycin sulfate, tetracycline	
	OTC Monograph Combinations	FM (Dec. 11, 1987)	combinations of antibiotic active ingredients (bacitracin, bacitracin zinc, neomycin sulfate, polymyxin B, oxytetracycline); combinations with 'caine'-type external analgesic ingredients	<a href="#">POLYSPORIN</a> bacitracin zinc/polylymyxin B
				<a href="#">NEOSPORIN PLUS</a> polymyxin B/neomycin/pramoxine
				<a href="#">BACTINE</a> bacitracin/neomycin/polymyxin B/ pramoxine

## J. Anorectal Products

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Local Anesthetics	OTC Monograph Single Ingredients	FM (Aug. 3, 1990)	benzocaine, benzyl alcohol, dibucaine, dyclinone, lidocaine, pramoxine, tetracaine	AMERICAINE benzocaine
				NUPERCAINAL dibucaine
Vasoconstrictor Active Ingredients	OTC Monograph Single Ingredients	FM (Aug. 3, 1990)	ephedrine, epinephrine, phenylephrine	
Protectant Active Ingredients	OTC Monograph Single Ingredients	FM (Aug. 3, 1990)	aluminum hydroxide gel, cocoa butter, glycerin, hard fat, kaolin, lanolin, mineral oil, petrolatum, topical starch, white petrolatum, calamine, cod liver oil, shark liver oil, zinc oxide	TUCKS TOPICAL STARCH SUPPOSITORIES topical starch
Analgesic, anesthetic, and antipruritic active ingredients	OTC Monograph Single Ingredients	FM (Aug. 3, 1990)	camphor, juniper, menthol	
Astringents	OTC Monograph Single Ingredients	FM (Aug. 3, 1990)	calamine, witch hazel (hamamelis water), zinc oxide	TUCKS WITCH HAZEL witch hazel
Kerolytics	OTC Monograph Single Ingredients	FM (Aug. 3, 1990)	alcloxa , resorcinol	
Anorectal Ingredient Combinations	OTC Monograph Combinations	FM (Aug. 3, 1990)	combinations of anorectal active ingredients	PREPARATION H CREAM glycerin/phenylephrine/pramoxine/ white petrolatum
				PREPARATION H SUPPOSITORIES cocoa butter/phenylephrine/shark liver oil
				TUCKS OINTMENT mineral oil/pramoxine/zinc oxide
				TRONOLANE CREAM pramoxine/zinc oxide
				TRONOLANE SUPPOSITORIES hard fat/phenylephrine
Hydrocortisone	OTC Monograph Single Ingredients	Final Rule (Aug. 26, 2003)	hydrocortisone	PREPARATION H HYDROCORTISONE

## K. Vaginal Antifungals

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Vaginal Antifungals	NDA	Nov. 30, 1990	clotrimazole	GYNE-LOTIMIN
		March 13, 1991	miconazole	MONISTAT
		Dec. 26, 1995	butoconazole	FEMSTAT
		Feb. 11, 1997	tioconazole	VAGISTAT

## L. Ophthalmics

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Ophthalmic Astringents	OTC Monograph Single Ingredients	FM (March 4, 1988)	zinc sulfate	
Ophthalmic Demulcents	OTC Monograph Single Ingredients	FM (March 4, 1988)	cellulose derivatives (carboxymethylcellulose sodium, hydroxyethyl cellulose, hydroxypropyl methylcellulose [hypromellose], methylcellulose), dextran 70, gelatin, polyols (glycerin, polyethylene glycol 300 & 400, polysorbate 80, propylene glycol), polyvinyl alcohol, povidone	GENTEAL EYE DROPS, ROHTO HYDRA hypromellose
				ADVANCED EYE RELIEF LUBRICANT glycerin
Ophthalmic Emollients	OTC Monograph Single Ingredients	FM (March 4, 1988)	lanolin preparations, oleaginus ingredients (light mineral oil, mineral oil, paraffin, petrolatum, white ointment, white petrolatum, white wax, yellow wax)	SOOTHE light mineral oil
Ophthalmic Hypertonicity Agents	OTC Monograph Single Ingredients	FM (March 4, 1988)	sodium chloride	MURO
Ophthalmic Vasoconstrictors	OTC Monograph Single Ingredients	FM (March 4, 1988)	ephedrine, naphazoline, phenylephedrine, tetrahydrozoline	VISINE ORIGINAL tetrahydrozoline
	NDA	Mar. 31, 1989	oxymetazoline	VISINE L.R.
		June 08, 1994	pheniramine/naphazoline	OPCON-A, VISINE-A
		Jul. 11, 1994	antazoline/naphazoline	VASOCON
Ophthalmic Antihistamines	NDA	Oct. 19, 2006	ketotifen	ZADITOR, CLARITIN EYE
Eyewashes	OTC Monograph Single Ingredients	FM (March 4, 1988)	water, tonicity agents, agents for establishing pH and buffering to achieve the same pH as tears, preservatives	ADVANCED EYE RELIEF EYE WASH purified water
Ophthalmics Combinations	OTC Monograph Combinations	FM (March 4, 1988)	combinations of ophthalmic active ingredients	CLEAR EYES SENSITIVITY dextran/hypromellose
				CLEAR EYES OINTMENT mineral oil/white petrolatum
				ROHTO COOL polysorbate/naphazoline

## M. Otics (Ear Wax Removal Aids)

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Earwax Removal Aids	OTC Monograph Single Ingredients	FM (Aug. 8, 1986)	carbamide peroxide	DEBROX, MURINE

N. Oral Healthcare Products

exclude all toothpastes as an OTC/cosmetic

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Anticaries	OTC Monograph Single Ingredients	FM (Nov. 6, 1995)	sodium fluoride	COLGATE, AIM, ACT, AQUAFRESH, CREST, MENTADENT, REMBRANDT
			sodium monofluorophosphate	COLGATE, AIM, SENSODYNE, AQUAFRESH, REMBRANDT
			stannous fluoride	CREST PRO-HEALTH
Anesthetics/ Analgesics	OTC Monograph Single Ingredients	TFM (Jan. 27, 1988)	benzocaine	COLGATE ORABASE, ORAJEL, ANBESOL, KANK-A
			benzyl alcohol	ZILACTIN
			dyclinone	SUCRETS ORIGINAL
			hexylresorcinol	S.T. 37
			menthol	
			phenol	CHLORASEPTIC SPRAY
		TFM (Sept. 24, 1991)	butacaine	
			salicylic alcohol	
Oral Astringents	OTC Monograph Single Ingredients	TFM (Jan. 27, 1988)	alum	
			zinc oxide	
Debriding Agents/ Oral Wound Cleansers	OTC Monograph Single Ingredients	TFM (Jan. 27, 1988)	carbamide peroxide in anhydrous glycerin	
			hydrogen peroxide	COLGATE PEROXYL, ORAJEL
			sodium bicarbonate	
			sodium perborate monohydrate	
Oral Demulcents	OTC Monograph Single Ingredients	TFM (Jan. 27, 1988)	elm bark, gelatin, glycerin, pectin	
Oral Mucosal Protectants	OTC Monograph Single Ingredients	TFM (Jan. 27, 1988)	compound benzoin tincture	
			benzoin tincture	
Tooth Desensitizers	OTC Monograph Single Ingredients	TFM (Sept. 24, 1991)	potassium nitrate	SENSODYNE, CREST SENSITIVITY
		FM pending	stannuous fluoride	CREST PRO-HEALTH



# N. Oral Healthcare Products

continued

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Antigingivitis/ Anti plaque Ingredients	OTC Monograph Single Ingredients	ANPR (May 29, 2003)	cetylpyridinium chloride	AIM, ACT, CREST, ORAJEL
	OTC Monograph Combinations	ANPR (May 29, 2003)	combination of eucalyptol, menthol, methyl salicylate, and thymol	LISTERINE
	NDA	July 11, 1997	sodium fluoride/triclosan	COLGATE TOTAL
Oral Healthcare Ingredient Combinations	OTC Monograph Combinations	ANPR (May 29, 2003)	combinations of oral healthcare active ingredients	SUCRETS, ORAJEL menthol/pectin
				CEPACOL, CHLORASEPTIC LOZENGES menthol/benzocaine
				CHLORASEPTIC phenol/glycerin

# O. Menstrual Products

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Menstrual Products	OTC Monograph Single Ingredients	TFM (Nov. 16, 1988)	pamabrom [diuretic]	
			ammonium chloride [diuretic]	
			caffeine [diuretic]	
			antihistamines reserved	
			muscle relaxants reserved	
	OTC Monograph Combinations	TFM (Nov. 16, 1988)	combinations of diuretics with analgesics	WOMEN'S TYLENOL acetaminophen/pamabrom
				PAMPRIN acetaminophen/pamabrom/pyrilamine [antihistamine]
				MIDOL acetaminophen/caffeine/pyrilamine [antihistamine]
				DIUREX magnesium salicylate/caffeine
			ammonium chloride with caffeine or pamabrom	

## P. Contraceptives

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Vaginal Contraceptives	OTC Monograph Single Ingredients	FM pending	nonoxynol-9	ORTHO OPTIONS, GYNOL II
	NDA	April 1, 1983	nonoxynol-9	TODAY
Emergency Contraceptives	NDA	Aug. 24, 2006	levonorgestrel	PLAN B

## Q. Nicotine Replacement Therapy

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Nicotine Oral (Gum)	NDA	Feb. 9, 1996	nicotine polacrilex	NICORETTE
Nicotine Oral (Lozenge)	NDA	Oct. 31, 2002	nicotine polacrilex	COMMIT
Nicotine Transdermal Systems	NDA	July 3, 1996	nicotine	NICODERM, HABITROL

## R. Weight Loss Aids

Product Category	Regulatory Route	Monograph Status/ Date of NDA OTC Approval	Active Ingredients	BRAND EXAMPLES
Weight Loss Aids	NDA	Feb. 7, 2007	orlistat	ALLI



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